## REMARKS/ARGUMENTS

Claims 1-49 are pending in the present application. In the Office Action, claims 4, 16-22 and 31-49 were withdrawn from consideration and claims 1-3, 5-15 and 23-30 were rejected. Claims 1 and 3 have been amended and new claims 50-55 have been added. Claims 2, 5 and 31-49 have been cancelled. No new matter has been added. Applicants respectfully request re-examination and reconsideration of the pending claims.

Election/Restriction

Applicants acknowledge withdrawal of claims 16-22 and 31-49 without traverse. However, Applicants traverse the withdrawal of claim 4 which recites the interventional device of claim 2 wherein the collar comprises a seal in communication with the at least one passage for inhibiting leakage of blood around the proximal extremity. In the Office Action, the Examiner indicated that the elected species of Figs. 4A-4C does not include a seal. Figs. 4A-4C illustrate an embodiment of a wire guide 80A in collar 26 (paragraph [0046] of application as filed). Collar 26 is described in paragraph [0044] of the application as filed and specifically states that:

> "[p]referably, first and second channels 70, 72 are configured to provide a slidable, sealed fit with guidewire tube 14 and catheter body 12 so as to minimize blood leakage therethrough. Optionally, elastomeric seals or valves (not shown) may be provided in one or both of channels 70, 72 to seal against the exterior of guidewire tube 14 and catheter body 12 to further inhibit blood leakage."

Therefore, the elected species of Figs. 4A-4C may include a seal and Applicants respectfully request that the withdrawal of claim 4 be removed and claim 4 considered during prosecution.

Claim Rejections Under 35 U.S.C. § 102

Claims 1, 15, 27 and 30 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,490,837 to Blaeser et al. (hereinafter referred to as Blaeser). Such rejection is overcome for the following reasons.

Independent claim 1 as amended now recites in part a collar having a distal portion with a distal end positionable in the vascular penetration and a proximal portion adapted to remain outside the vascular penetration, the collar having a first longitudinal passageway configured to slidably receive the proximal extremity of the catheter shaft without substantial leakage of blood therethrough, and a second longitudinal passageway configured to slidably receive the proximal end of the guidewire tube without substantial leakage of blood therethrough, wherein the first passageway is discrete from the second passageway from the distal end through at least part of the proximal portion. Support for this amendment may be found *inter alia* in dependent claims 2 and 5, along with Figs. 2A, 2B, 3A and 5A of the application as filed, therefore no new matter has been added. The cited Blaeser reference fails to teach or suggest this newly added limitation.

Blaeser discloses a balloon dilation catheter having an elongated guide lumen for slidably receiving a conventional guidewire (col. 7, line 54 – col. 8, line 59). Proximal and distal seal members 62 and 64 have a passageway for slidably receiving the guide lumen (col. 9, lines 43-46). However, seal members 62 and 64 only receive the guidewire lumen and do not slidably receive the catheter shaft. Therefore the cited reference fails to teach or suggest a collar having a first longitudinal passageway configured to slidably receive the proximal extremity of the catheter shaft without substantial leakage of blood therethrough, as amended claim 1 now requires. Furthermore, there is only a single passageway in seal members 62, 64, hence Blaeser also fails to disclose two passageways, wherein the first passageway is discrete from the second passageway from the distal end through at least part of the proximal portion, as required by claim 1.

Because a single reference fails to disclose, teach or suggest all of the limitations of claim 1, anticipation cannot be established under 35 U.S.C. § 102(b). Applicants respectfully request that the 35 U.S.C. § 102(b) rejection be withdrawn and independent claim 1 allowed along with the claims depending therefrom.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-3, 5-15 and 23-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,800,065 to Duane et al. (hereinafter referred to as Duane) in view of Blaeser. Such rejection is overcome for the following reasons.

As discussed above, independent claim 1 has been amended to recite in part a collar having a distal portion with a distal end positionable in the vascular penetration and a proximal portion adapted to remain outside the vascular penetration, the collar having a first longitudinal passageway configured to slidably receive the proximal extremity of the catheter shaft without substantial leakage of blood therethrough, and a second longitudinal passageway configured to slidably receive the proximal end of the guidewire tube without substantial leakage of blood therethrough, wherein the first passageway is discrete from the second passageway from the distal end through at least part of the proximal portion. Support for this amendment was discussed above. Both Duane and Blaeser alone or in combination fail to teach or suggest this newly added limitation.

Duane discloses a catheter having a guide wire lumen with a guide way extending along the length of a stiffened proximal shaft portion and a guide member slidably disposed about the proximal shaft for directing a guidewire into or out of the guide way and the guidewire lumen (Abstract). In Duane, the proximal end of guide member 32 has separate passageways for the guidewire and catheter shaft (Fig. 12). However, the passageway for the guidewire merges into the passageway for the catheter shaft near the distal end of the guide member (Fig. 12). Therefore, Duane fails to disclose that the two passageways are discrete from one another as required by claim 1 which recites in part that the first passageway is discrete from the second passageway from the distal end through at least part of the proximal portion. This aspect of the present invention is advantageous in that separate passageways help prevent entanglement of the guidewire with the catheter shaft due to twisting or rotation during delivery and also allow a hemostatic seal to be created in each passageway as well as permitting a hemostasis valve to easily seal over the uniform arcuate surface of the collar, rather than having to seal against the non-uniform "figure eight" surface created by the catheter shaft and the guidewire.

Blaeser also fails to disclose this missing limitation. As discussed *supra* Blaeser discloses a balloon dilation catheter having an elongated guide lumen for slidably receiving a conventional guidewire (col. 7, line 54 – col. 8, line 59). Proximal and distal seal members 62 and 64 only receive the guidewire lumen and do not slidably receive the catheter shaft. Therefore Blaeser fails to disclose a collar having a first longitudinal passageway configured to slidably receive the proximal extremity of the catheter shaft without substantial leakage of blood therethrough, and a second longitudinal passageway configured to slidably receive the proximal end of the guidewire tube without substantial leakage of blood therethrough, as required by amended claim 1. Also, since Blaeser fails to disclose two separate passageways, the cited reference does not teach or suggest that the first passageway is discrete from the second passageway from the distal end through at least part of the proximal portion, as required by amended claim 1.

Moreover, in the Office Action, the Examiner argued that it would have been obvious to one or ordinary of skill in the art at the time the invention was made to configure the wire guide of Duane for use with a co-axial type of guidewire exchange catheter as taught by Blaeser. However, Duane requires a guide way slit in the catheter shaft in order to allow a guidewire to enter and exit the guidewire lumen in the catheter shaft. The guidewire tube in Blaeser does not have a slit. Placing a slit in the guidewire tube of Blaeser would render the resulting combination inoperative because the guidewire tube has a distal end in the patient and a proximal end outside of the patient. A slit in the guidewire tube would permit blood to leak from the proximal portion of the guidewire tube outside the patient.

Additionally, Blaeser teaches away from guidewire tube modifications such as slitting. Blaeser teaches that the guidewire tube provides additional support for manipulating the guidewire when the guidewire is initially advanced in the vessel prior to insertion of the catheter in the vessel, as well as providing support for the guidewire after the catheter has been inserted into the vessel (col. 6 lines 16-24). Slitting the guidewire tube allows the guidewire to exit from the guidewire tube, thereby reducing the support provided by the guidewire tube to the guidewire thus defeating the purpose of Blaeser's guidewire tube. The combination of Duane and Blaeser is improper and constitutes impermissible hindsight reconstruction. The claimed invention as a

whole, not just its individual elements must be considered and it is inappropriate to use hindsight guided by the applicant(s)'s disclosure. M.P.E.P. § 2141.

Regarding claims 26 and 29, Applicants traverse the 35 U.S.C. § 103(a) rejection for the following reasons. Neither Duane nor Blaeser teach or suggest that a sheath may be selectively positioned to deploy a first selected number of stent segments from the catheter shaft while retaining a second selected number of stent segments on the catheter shaft, as required by claim 26. In fact, the term "stent" does not even appear in Blaeser's disclosure and there is no analogous structure disclosed in the reference. Additionally, neither of the cited references teach that a sheath may be selectively positioned to expand a first portion of the balloon while constraining a second portion of the balloon, as claim 29 requires. Therefore, because the cited references alone or in combination fail to teach or suggest each and every element of the claim, *prima facie* obviousness cannot be established and Applicants respectfully request withdrawal of the § 103(a) rejection of claims 26 and 29.

New Claims

Claims 50-55 have been added. Support for claims 50-54 may be found in paragraphs 0039, 0041 and 0042, therefore no new matter has been added. Claims 50-54 are believed to be patentable over the cited references because they depend from independent base claim 1 which has been distinguished from the cited references *supra*.

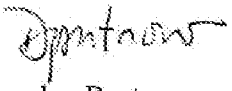
Support for independent claim 55 may be found in dependent claims 26-29 of the application as originally filed, therefore no new matter has been added. Claim 55 is believed to be patentable over the cited references because in both Duane and Blaeser, the entire balloon is deployed. Therefore, the cited references all fail to teach or suggest an interventional element having a selectable length adapted to be deployed at the treatment site while a remaining length of the interventional element remains undeployed and coupled to the distal extremity of the catheter shaft.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Additionally, a Supplemental IDS has been submitted for consideration by the Examiner during prosecution of this application.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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